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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,422	02/27/2004	Boris Y. Shekunov	FER-14668.001	5255
7609	7590	11/20/2007	EXAMINER	
RANKIN, HILL, PORTER & CLARK, LLP			DRODGE, JOSEPH W	
925 EUCLID AVENUE, SUITE 700			ART UNIT	PAPER NUMBER
CLEVELAND, OH 44115-1405			1797	
			MAIL DATE	DELIVERY MODE
			11/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/789,422	SHEKUNOV ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joseph W. Drodge	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 October 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9, 11-14 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9, 11-14 and 17-29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

Claims 1-9,11-14 and 17-29 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant Specification does not support claiming of the supercritical fluid remaining in supercritical fluid remaining in a supercritical state while the first fluid is flowed outside of the extraction chamber. The Specification also does not support the contrary recitations within claims 1 and 9 of the aqueous particulate suspension from extraction chamber to collection vessel, with such suspension not being formed or yielded until the later step of draining of collection vessel occurs. Such recitations within independent claims 1,11 and 17 therefor constitute New Matter.

Claims 1-9 and 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In each of claims 1 and 9, it is not understood what the fluid or material is which is separately flowed from the aqueous particulate suspension. It is also not understood how the aqueous suspension is formed in the extraction chamber and flowed to the collection vessel, since it is now claimed that such suspension is not formed or yielded until the later step of draining of the collection vessel.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999

(AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 1-9,11-14 and 17-29 are rejected under 35 U.S.C. 102(e, f and g) as being anticipated by Chattopadhyay et al patent 7,083,748, as fully supported by Provisional Application 60/445,944 filed 2/7/2003 and enclosed with this Office Action.

The applied reference shares common inventors with the instant application, however constitutes a separate inventive entity since it omits inventorship of Robert W. Huff. Based upon

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the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Chattopadhyay et al disclose producing of particles comprising providing supercritical fluid, 1<sup>st</sup> solvent soluble in such fluid, 2<sup>nd</sup> insoluble solvent, the 2<sup>nd</sup> solvent optionally being partially soluble in the 1<sup>st</sup> solvent, and solute, contacting these together to form a solution, then contacting the solution with supercritical fluid to extract 1<sup>st</sup> solvent from the solution and precipitate the solute in the form of particles suspended in the 2<sup>nd</sup> solvent (all disclosed at figures 1 and 3, column 6, line 31-column 7, line 40, column 7, lines 5-8 indicate that the solution of solvents and solute are formed before contacting with supercritical fluid). Plural solvents having various miscibility with each other and with supercritical fluid are used (column 6, lines 50-62). Also see column 10, lines 19-51 concerning use of secondary co-solvents and formation of aqueous dispersions.

Such dispersion may, in a preferred embodiment comprise particles of solid or liquid and may comprise the dissolved substance in solution or suspension, optionally in any of various organic solvents (column 6, lines 58-61).

Patent '748 also discloses separation of particulate suspension from solvent(s) by flowing of the solvent(s) from extraction chamber to downstream chambers and/or collection vessels. Such flowing is separate from flow of other solvents and supercritical fluid which may be flowed in counterflow. Supercritical fluid(s) are maintained at elevated temperatures and pressures of supercritical values while flowing between chambers by plural pumps and valves Flow into and out of the collection chambers is controlled by valves, thus facilitating selective isolation of the collection chambers and selective draining to form particles and retrieve aqueous suspension.

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(See especially column 9, line 17-column 10, line 19 and column 11, lines 16-35 and column 11, line 60-column 12, line 8).

Patent '748 also discloses the following with respect to various dependent claims: biologically active substances and excipients (column 6, line 62-column 7, line 14), use of carbon dioxide (column 7, lines 26-27), plural solutes (emulsions , dispersed or dissolved material/ column 6, lines 15-30) , choice of organic solvent materials (column 6, lines 57-61), second solvent being water (column 6, lines 18-19), particle size ranging to 10 nanometers,

Applicant's arguments with respect to claims 1-9, 11-14 and 17-29 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

JWD

November 17, 2007

  
JOSEPH DRODGE  
PRIMARY EXAMINER